Registration Decision RD2015-09

Sulfoxaflor

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Registration Decision for Sulfoxaflor

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Isoclast Active, Transform WG Insecticide and Closer Insecticide, containing the technical grade active ingredient sulfoxaflor, to control or suppress aphids, leafhoppers, San Jose scale and Lygus bug on field vegetable, cereal grain, oilseed, fruit and nut crops.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2015-08, *Sulfoxaflor*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for sulfoxaflor and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2015-08. This decision is consistent with the proposed registration decision stated in PRD2015-08.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2015-08, *Sulfoxaflor* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "... the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website.

What Is Sulfoxaflor?

Sulfoxaflor is a compound in the sulfoximine class of chemistry. It is an insecticide with systemic activity in plants, being translocated through the xylem, and is effective against sap-feeding insects both on contact and through ingestion. It acts on the same type of insect nerve cell receptor as the neonicotinoid insecticides, but in a different way, so it is considered to have a different mode of action and has been classified into a separate subgroup. Foliar application of end-use products containing sulfoxaflor provides control or suppression of aphids, leafhoppers, San Jose scale and Lygus bugs on field vegetable, cereal grain, oilseed, fruit and nut crops.

Health Considerations

Can Approved Uses of Sulfoxaflor Affect Human Health?

Products containing sulfoxaflor are unlikely to affect your health when used according to label directions.

Potential exposure to sulfoxaflor may occur through the diet (food and water), when handling and applying end-use products containing sulfoxaflor, or when re-entering treated areas. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

In laboratory animals, sulfoxaflor was demonstrated to be of slight to moderate toxicity via the oral route; therefore the signal word and hazard statement "WARNING – POISON" are required on the label. Sulfoxaflor was demonstrated to be of low toxicity via the dermal and inhalation routes. It was minimally irritating to eyes and skin, and did not cause an allergic skin reaction.

The end-use product, Transform WG Insecticide, was demonstrated to be of low toxicity via the oral, dermal and inhalation routes of exposure in laboratory animals. It was moderately irritating to eyes; therefore, the signal word and hazard statement "WARNING – EYE IRRITANT" are required on the label. Transform WG Insecticide was minimally irritating to the skin and did not cause an allergic skin reaction. Closer Insecticide was demonstrated to be of low acute toxicity via the oral and dermal routes in laboratory animals, and is not expected to pose an acute inhalation hazard. It was minimally irritating to the eyes and non-irritating to the skin, and did not cause an allergic skin reaction.

Health effects in animals given repeated doses of sulfoxaflor included effects on the liver, the nervous and muscular systems, and the male reproductive system. Sulfoxaflor did not damage genetic material. There was evidence of tumours of the male reproductive system (preputial gland and testis) in the rat, but the increased tumour response was either marginal or occurred at very high doses. Liver tumours observed in rodents were deemed to occur via a mode of action that is not relevant to humans.

When sulfoxaflor was given to pregnant or nursing animals, effects on the developing fetus (limb abnormalities) and juvenile animal (neonatal deaths) were observed at doses that were not toxic to the mother, indicating that the young were more sensitive to sulfoxaflor than the adult animal. The risk assessment takes this sensitivity into account in determining the allowable level of human exposure to sulfoxaflor.

The risk assessment protects against the effects of sulfoxaflor by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern

Aggregate dietary intake estimates (food plus water) revealed that infants, the subpopulation which would ingest the most sulfoxaflor relative to body weight, is expected to be exposed to less than 86 % of the acceptable daily intake (ADI). Based on these estimates, the chronic dietary risk from sulfoxaflor is not of concern for all population sub-groups except for females 13-49 years. For this sub-group, the ADI from exposure to sulfoxaflor is not the same as that for water, hence, an aggregate dietary intake estimate (food plus water) could not be conducted. The chronic risks from food and water are less than 9 % and 20 % of the ADI, respectively. Sulfoxaflor is not carcinogenic; therefore a cancer dietary exposure assessment is not required.

The acute reference dose (ARfD) for females 13-49 years from exposure to sulfoxaflor residues in water is not the same as that for food, hence an aggregate dietary intake estimate (food plus water) could not be conducted. For this subgroup, the acute dietary risk from food and water exposure to sulfoxaflor is 117 % and 6.61 %, respectively, at the 99.9th percentile of exposure. For all other population subgroups, the deterministic acute dietary exposure (food plus water) is expected to be less than 21 % of the ARfD. Consequently, a single dose of sulfoxaflor is not likely to cause acute health effects to any population subgroup (including infants and children) in light of the conservatisms inherent in the risk assessment (i.e. exposure to all treated crops co-occuring on the same day).

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada, the United States, the European Union, Australia, Brazil, and New Zealand using sulfoxaflor on various fruits, vegetables, oilseeds, cereal grains, tree nuts, and legumes were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation of Proposed Registration Decision PRD2015-08, *Sulfoxaflor*.

Risks in Residential and Other Non-Occupational Environments

Exposures of the general public are considered acceptable when entering orchards to pick pome and stone fruits treated with Closer Insecticide.

Exposure of the general population to residues of sulfoxaflor from treated orchards could occur by participating in pick-your-own activities in pome fruit (apple and pear) and stone fruit (peach, nectarine, plums, and cherry) orchards. The exposures from such activities are considered acceptable for adults, youths, and children.

Occupational Risks From Handling Transform WG Insecticide and Closer Insecticide

Occupational risks are not of concern when Transform WG Insecticide and Closer Insecticide are used according to the proposed label directions, which include protective measures.

Farmers and custom applicators who mix, load or apply Transform WG Insecticide and Closer Insecticide, as well as field workers re-entering freshly treated fields and orchards, can come in direct contact with sulfoxaflor residues on the skin. Therefore, the label specifies that anyone mixing and loading Transform WG Insecticide and Closer Insecticide, and during clean-up and repair must wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes plus socks, and eye protection. In addition, when mixing and loading for aerial application, workers must also wear coveralls. Applicators must wear a long-sleeved shirt, long pants, and shoes plus socks. In addition, all mixers and loaders must wear eye protection, and for aerial applications, an added

layer of coveralls must be worn for mixing and loading. The label also requires that workers not enter treated fields for 12 hours after application. Taking into consideration these label statements, the number of applications, and the duration of exposure for workers, the risks to these individuals are not a concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Sulfoxaflor Is Introduced Into the Environment?

When used according to label directions, sulfoxaflor is not expected to pose an unacceptable risk to the environment.

When sulfoxaflor is applied as a foliar spray, this compound will move from the surface of the leaf to internal leaf tissue. Sulfoxaflor can be deposited directly on pollen and nectar if applied when plants are in bloom. Sulfoxaflor is systemic and therefore can also reach pollen and nectar through its movement inside the plant. When spray droplets reach the soil, sulfoxaflor is rapidly broken down by soil microbes. Sulfoxaflor transformation products that are formed in soil are persistent and have the potential to leach through the soil profile and enter groundwater. When sulfoxaflor enters surface water, it also breaks down in the presence of microbes, albeit more slowly than in soil.

Sulfoxaflor poses negligible risk to birds and mammals, fish, terrestrial and aquatic plants and aquatic invertebrates. Because sulfoxaflor is an insecticide, it may cause adverse effects to certain non-target insects when they come in contact with high enough residue levels on plants. Therefore, in order to reduce exposure and minimize potential risk to beneficial arthropods precautionary statements appear on product labels. While sulfoxaflor is unlikely to pose a risk to bee colonies it may pose a potential risk to adult foraging bees exposed directly to spray droplets or to fresh residues on plants, however these effects are relatively short-lived, lasting approximately three days or less. When the risk reduction measures included on the label are followed, risks to bees are considered to be acceptable.

Value Considerations

What Is the Value of Transform WG Insecticide and Closer Insecticide?

Transform WG Insecticide and Closer Insecticide provide control or suppression of certain sap-feeding insect pests of listed field vegetable, cereal grain, oilseed, fruit and nut crops.

Transform WG Insecticide may be applied using either ground-based or aerial application equipment to control aphids and Lygus bugs on cereal grains and oilseeds. Closer Insecticide may be applied using ground-based application equipment, and also by aerial application equipment on potatoes, to control or suppress aphids, leafhoppers and San Jose scale on field vegetable, fruit and nut crops.

The active ingredient sulfoxaflor acts on the same type of insect nerve cell receptor as the neonicotinoid insecticides but in a different way, so it is considered to have a different mode of action and has been classified into a separate subgroup. Insects resistant to neonicotinoids have not shown cross-resistance to sulfoxaflor, giving this new active ingredient value for insecticide resistance management.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Transform WG Insecticide and Closer Insecticide to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with sulfoxaflor on the skin or through inhalation of spray mists, anyone mixing and loading Transform WG Insecticide and Closer Insecticide, and during clean-up and repair, must wear a long-sleeved shirt, long pants, chemical-resistant gloves, shoes plus socks, and eye protection. In addition, when mixing and loading for aerial application, workers must also wear coveralls. Applicators must wear a long-sleeved shirt, long pants, and shoes plus socks. In addition, a standard label statement to protect against drift during application was added to the label. The label also requires that workers not enter treated fields for 12 hours after an application. Taking into consideration these label statements, the number of applications, and the duration of exposure for workers, the risks to these individuals are not a concern.

Environment

Sulfoxaflor product labels inform the user of the leaching potential of sulfoxaflor transformation products and of the hazard to bees and beneficial arthropods. To minimize the exposure to bees and bee brood, the label specifies that sulfoxaflor must be applied early in the morning or late in the evening when bees are not active and must not be applied during bloom on most crops. Taking these use restrictions into consideration, the risk to bees is not of concern.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2015-08, *Sulfoxaflor*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.